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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/692,634	10/19/2000	Paul John Rennie	8308	8314

27752 7590 07/02/2007

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EXAMINER	
WILLIAMS, LEONARD M	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
07/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/692,634	RENNIE ET AL.	
	Examiner	Art Unit	
	Leonard M. Williams	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,20-27 and 30-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7, 20-27 and 30-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Response to Amendment

Applicant's amendment received 02/07/2007 amending the specification at page 5, line 20 and page 6. line 1 has been entered. As such the objection to the specification of the last office action is withdrawn.

No amendment to the claims have been made.

Claims 1-7, 20-27 and 30-37 are pending.

Response to Arguments

Applicant's arguments filed 02/07/2007 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument on page 4 of the remarks, that "assuming *arguendo* that one having ordinary skill in the art would combine the disclosures....one would still fall short of the of Applicants' claimed invention only to arrive at a composition that comprises vitamin C, glutaric acid and zinc that utilizes pyroglutamic acid to

enhance drug delivery and inactivates RV-14 and several other strains of human rhinoviruses by a mode of action independent of acidic pH at low temperatures.", the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

In response to applicant's assertion on pages 3-4 that the prior art does not teach organic acids having pKas from about 3.0-5.0 or solutions having pH values of 3.5-5.5 the examiner respectfully points out that the combined references teach the equivalent compounds as claimed and that properties such as pKa and pH are inherent to the organic acids (ascorbic acid-Vitamin C-pKa=4.21; and solutions themselves. Further it is simple routine optimization to adjust pH for one of ordinary skill in the art as presented in the last office action.

The examiner respectfully points applicant's to the "Dissociation Constants of Organic Acids and Bases", in CRC Handbook of Chemistry and Physics, Internet Version 2007 (87th Edition), David R. Lide, ed., Taylor and Francis, Boca Raton, FL. pp.8-44 and 8-46 where the pKa's of pyroglutamic, glutaric and ascorbic acid are found. All are within the pKa requirement of 3.0-5.0 of the organic acids as claimed. This is included in support of the inherency of the compounds properties.

For the reasons cited above and for the reasons of record the 103(a) rejection of the last office action is maintained. A copy of the rejection is included below. This action is **Final**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 20-27 and 30-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deihl (EP0505374B1), in view of Makino et al. (US Patent No. 4789667) and further in view of Kuhrt et al. (Virucidal Activity of Glutaric Acid and Evidence for Dual Mechanism of Action, Antimicrobial Agents and Chemotherapy, Dec. 1984, pp. 924-927).

Deihl teaches, on page 2, a pharmacological composition for treatment of the common cold by spraying said composition into the oral cavity (with mucosal absorption of the composition posited as the means of administration). The composition comprises vitamin C (ascorbic acid) and a non-toxic zinc salt. In example I Table 1 Deihl teaches a suitable zinc-vitamin C composition that includes pharmaceutical grade water, ascorbic acid (1.64% by weight), sodium bicarbonate (0.14% by weight), glycerine, potassium sorbate, EDTA, zinc gluconate (1.09% by weight), L-lysine, glycine, fruit juice, sucrose, magnasweet, tween-80, trace bioflavonoids, orange flavoring and peppermint oil.

Deihl does not teach direct spraying of the composition into the nasal turbinates, or the use of pyroglutamic acid in the composition.

Makino et al. teach, in the abstract, a pharmaceutical composition for external use with enhanced penetration of a pharmacologically active agent through the skin or mucosa, said composition comprising a pharmacologically active agent and an optically active or inactive pyroglutamic acid ester.

In col. 3 lines 55-65, Makino et al. teach that in US Patent No. 4434159 a drug which is substantially unabsorbable through the mucosa of the rectum is made

absorbable through the rectal mucosa by co-administration with a penetration enhancer (pyroglutamic acid or a salt thereof).

Makino et al. teach, in col. 12 lines 17-40, that the compositions contain the penetration enhancer in an amount of from 0.2-25% by weight, preferbly 0.5-12% by weight based on the total weight of the composition. Further the mucosa may be that of the rectum, oral cavity, nasal cavity or vagina.

Makino et al. teach, in col. 14 line 1 to col. 15 (table 2 comparison 16 and 17), ointments prepared from 1 part of nifedipine, 10 parts L-pyroglutamic acid (comparison 1) or 10 parts DL-pyroglutamic acid (comparison 2), 89 parts of a gel ointment base (composed of 1 part of Carbopol 934-a mucoadhesive agent as defined in the current specification page 8 lines 1-10, 12 parts of propylene glycol, 30 parts ethanol, 1 part diisopropanolamine and 56 parts water). Thus the penetration enhancer (L-pyroglutamic acid or DL-pyroglutamic acid) is present in 10% by weight, the Carbopol 934 is present in 1% by weight, and the pharmacologically active agent is present in 1% by weight.

Kuhrt et al. teach, in the abstract, that Rhinoviruses as a group are notably sensitive to inactivation in solutions with a pH of less than 5.3. On page 924, Kuhrt et al. teach that glutaric acid (one of the organic acids currently claimed) has been demonstrated as an effective virucidal agent against rhinovirus on human skin.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the ointment composition of Makino et al. comprising a penetration enhancer (pyroglutamic acid) and ointment base (that could be applied to

mucosa of the rectum, oral cavity, nasal cavity or vagina), with the pharmacological composition of Deihl comprising ascorbic acid and zinc gluconate in order to formulate a composition for treatment of the common cold. One would be motivated to add the Makino et al. ointment compositions to the Deihl compositions in order to achieve enhanced penetration of the ascorbic acid and zinc gluconate and thus achieve a greater effectiveness against the common cold. One would be motivated to adjust the overall pH of the combined formulation to less than pH 5.3 as Kuhrt et al. has demonstrated that rhinoviruses are inactivated by acidic conditions wherein the overall pH is less than 5.3. One would further be motivated to use glutaric acid as an organic acid with the combined formulation either in conjunction with ascorbic acid or by itself in treating the common cold as Kuhrt et al. show that Glutaric acid is an effective virucide against rhinovirus (on human skin).

The examiner respectfully points out the following from MPEP 2144.06: "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re* Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

The determination of optimal viscosity, optimal pH ranges, and optimal pKa ranges are matters of routine experimentation.

The examiner respectfully points out the following from MPEP 2144.05: "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to

discover the optimum or workable ranges by routine experimentation." In *re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969); Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed.Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

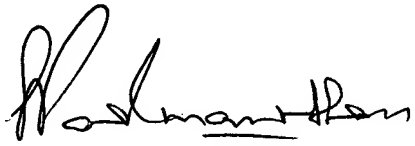
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M. Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LMW



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